

REMARKS

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith, which place the application into condition for allowance.

RESPONSE TO RESTRICTION REQUIREMENT

The August 19, 2002 Office Action required restriction under 35 U.S.C. 121, to the subject matter of one of the following groups:

- I. Claims 1-20, drawn to surgical methods comprising electromagnetic energy, classified in class 128, subclass 898; and
- II. Claims 21-22, drawn to a kit comprising a photosensitizer agent, classified in class 514, subclass 454.

In response, the invention of Group I, claims 1-20, drawn to surgical methods comprising electromagnetic energy, classified in class 128, subclass 898, is elected, with traverse, for further prosecution in this application. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The present invention relates to, *inter alia*, the photochemical bonding of tissues using at least one photosensitizing agent to form a tissue-photosensitizer complex and applying electromagnetic energy to said complex, thereby creating a tissue seal. The aforementioned photosensitizing agents are included in a kit claimed in Group II.

An application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents, and they are either independent or distinct. M.P.E.P. § 803. Additionally, if examination of the entire application can be made without serious burden to the examiner, then the application as a whole must be examined despite including claims to independent or distinct inventions. *Id.*

The Office Action states that the inventions are patentably distinct from each other because the inventions are related as process and apparatus for its practice. The Office Action contends that the two groups “are distinct if it can be shown that either 1) the process as claimed can be practiced by another materially different apparatus or by hand, or 2) the apparatus as claimed can be used to practice another and materially different process. M.P.E.P. § 806.05 (e). The Office Action states that “the apparatus can be used for staining the cornea,” in apparent

support of the apparatus as claimed being “used to practice another and materially different process.”

Applicants respectfully traverse. Contrary to the views expressed by the Examiner, the claims of Group I and II relate to the same inventive concept. The apparatus (i.e., kit) claimed in Group II is specially adapted to carry out the methods claimed in Group I.

A photosensitizer agent of the claimed kit (e.g., rose bengal, riboflavin-5-phosphate, *N*-hydroxypyridine-2-(1H)-thione), is cannot be used as a corneal stain. For example, rose-bengal is used clinically as a corneal stain to monitor conjunctival integrity, however, it is typically used in a more concentrated solution, much higher than that which is used in photochemical tissue bonding (PTB).¹ Therefore, at the low concentrations indicated for PTB, rose bengal is not an effective stain. When used clinically as a corneal stain, rose bengal can be readily detected—with the unaided eye—and its detection is used in a qualitative test that reflects the integrity of the corneal surface (van Bijsterveld, O.P. Arch. Ophthalmol. 1969; 82: 10-14; Prause, J.U. et al, J. Autoimmunity. 1989; 2:501-507). Example 1 of the present application states that rose bengal fluorescence was detected using confocal fluorescence spectroscopy, rather than the unaided eye. Moreover, riboflavin-5-phosphate and *N*-hydroxypyridine-2-(1H)-thione, for example, have not been previously characterized as effective corneal stains.

It is respectfully submitted that the Groups designated by the Examiner do not warrant separate examination and search, given that the requisite presentation of serious burden has not been made. Therefore, it is respectfully submitted that Groups I and II be searched, examined, and rejoined. Reconsideration and withdrawal of the requirement for restriction is respectfully requested.

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

The August 20, 2002 Office Action further required a species election between: i) the method performed *ex vivo*, and ii) the method performed *in vivo*. Applicants elect species ii, directed to the method performed *in vivo*, with traverse. The election of species is made with the understanding that the generic claims will be searched once the species is otherwise determined

¹ The indicated concentrations of rose bengal used for PTB range from 1 mM to 3 mM for corneal use, corresponding to a solution of about 0.1% to 0.3% (the Examiner is kindly referred to the Detailed Description, under “Photoactivation and Photosensitizers”).

to be patentable. M.P.E.P. 803.02. Applicants reserve the right to elect further species for prosecution, either in the present application or in divisional application(s).

Reconsideration and withdrawal of the species election requirement are respectfully requested in light of the remarks herein.

The requirement of species election is requested on the basis that the two species are patentably distinct. The Examiner states that the "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species...", but does not provide a reason as to what constitutes a distinction as a basis for requiring the species election.

It follows that there is a disclosed relationship between the claimed species in that each constitutes the utilization of the claimed method. The claimed method used *ex vivo* refers to the photochemical bonding technique, using photosensitiser agents, to anneal tissue. In other words, the claimed method used *ex vivo* ultimately results in its use *in vivo*, as claimed in Species ii. It is understood that the Examiner can broaden the search to include other species when there is a relationship among the species; *see* M.P.E.P. § 808.01(a), which states that "where there is no disclosure of relationship between species (see M.P.E.P. § 806.04(b)), they are independent inventions and election of one invention" is required. With regard to the instant invention, there is a disclosure of a relationship between the claimed species.

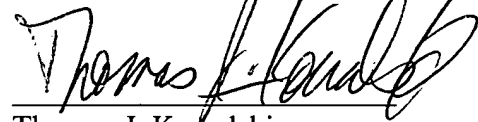
Accordingly, reconsideration and withdrawal of the species election requirement is respectfully requested.

CONCLUSION

The present restriction and election of species requirements, if maintained, will result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO. Restriction has not been shown to be proper, given the requisite showing of burden has not been made and there are relationships between the two species, and the two inventions of Groups I and II. The search and examination of each Group and species is likely to be co-extensive and would involve such interrelated art that the search and examination of the entire application can be made without unnecessary, undue or serious burden on the Examiner. Therefore, all of the preceding remarks mitigate against restriction. Reconsideration and withdrawal of the restriction and election of species requirements and favorable examination of all the Claims of Group I and II, and both species i and ii, on the merits, are respectfully requested.

Respectfully submitted,
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